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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,631	11/16/2005	Ruihua Chen	60289-USA	7138
<div>7590 John M Sheehan FMC Corporation 1735 Market Street Philadelphia, PA 19103</div>			<div>EXAMINER MONSHIPOURI, MARYAM</div>	
			<div>ART UNIT 1656</div>	<div>PAPER NUMBER</div>
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/26/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/528,631

Applicant(s)

CHEN ET AL.

Examiner

Maryam Monshipouri

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-5, 7 is/are rejected.
- 7) ☒ Claim(s) 3, 6 and 13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application. |
| Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: <u>See attachment</u> |

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Applicant's response to restriction requirement filed 11/03/2006 is acknowledged. Applicant elected Group I (claims 1-7 and 13) with traverse. Claims 8-12 are withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues the following: that even though said Groups are patentably distinct searches of each Group overlap and therefore examining Groups I-II together, does not impose an undue burden on the Office.

This argument was fully considered but was found **unpersuasive**. This is because the issue here is that the special technical feature of each invention is separate and unrelated. The search of Group I invention requires a search in nucleic acid databases which cannot be solely relied upon for searching Group II invention. Therefore, as applicant can appreciate, the searches of said Groups are **not coextensive** and rejoinder of Groups I-II inventions **does impose an undue burden** of searching on the examiner.

In conclusion, in view of the response provided here, in addition to comments provided previously, lack of unit is maintained and is hereby made **Final**.

DETAILED ACTION

Claims 1-7 and 13 are under examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-2, 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids encoding complete amino acid sequence of SEQ ID NO:2, does not reasonably provide enablement for any fragments of said nucleic acids having at least 10 nucleotides with no specific function.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2n 1400 (Fed. Cir. 1988) are: 1) the quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breadth of the claims.

The disclosure fails to teach which residues in DNA sequences encoding full-length SEQ ID NO:2 is in charge of assigning function to their expression products. No examples of such residues are provided either. Current state of the art indicates that for a DNA sequence (fragment) to encode any product with function it must comprise more than 10 nucleotides and current prior art is totally unpredictable as what the other residues of such DNA sequence may be.

Therefore, due to lack of sufficient guidance and examples provided and due to unpredictability of prior art as to which other nucleotides besides those 10 bases from DNA sequences encoding SEQ ID NO:2 must be incorporated in fragments claimed (see claims 1-2), one of skill in the art has to go through burden of undue experimentation to screen for those DNA fragments that encode products with kinase activity and as such the claims go beyond the scope of the disclosure.

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Since DNA fragments of SEQ ID NO:1 (and/or those encoding SEQ ID NO:2) are not enabled, vectors comprising said products (claim 7) are not enabled either.

Claims 1-2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 (and its dependent claim 7) and claim 2 as recited, are directed to a **genus** of fragments having at least 10 bases of DNA sequences encoding SEQ ID NO:2, which have been merely defined by structure.

The specification does not contain any disclosure of the function of all DNA fragments that need to comprise only 10 nucleotides of those encoding SEQ ID NO:2. The genus of cDNAs that comprise these above cDNA molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The disclosure only provides a **single species** (namely DNA sequences encoding SEQ ID NO:2) of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

Since fragments of claim 1 are inadequately described, vectors comprising said products (claim 7) are also inadequately described.

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Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Daley et al. (J. Mol. Biol., 279, 201-210, 1998). Daley teaches a fragment having or consisting of at least 10 nucleotides of a sequence encoding SEQ ID NO:2 (see attached sequence alignment and residues 417-429 of Daley), anticipating claims 1-2. In page 208, Daley teaches about cloning its DNA sequences which inherently require preparation of expression vectors comprising its DNA sequences anticipating claim 7.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Olek et al. (US20040241651A1, issued 12/2004). Olek teaches several nucleic acid molecules consisting of a fragment of SEQ ID NO:1, having at least 13 nucleotides (see the attached alignment), anticipating claims 4-5 of this invention.

Allowable Subject Matter

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Claims 3, 6, and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This is because nucleic acids encoding SEQ ID NO:2 or consisting of a fragment of SEQ ID NO:1 having 15-50 nucleotides are free of prior art. Further the prior art does not teach or suggest preparing such specifically claimed products. Therefore, said products are also non-obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571) 272-0932. The examiner can normally be reached on 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

M. Monshipouri
Maryam Monshipouri Ph.D.

Primary Examiner

Result 1
US 10-257-017B-4121

```

; Sequence 4121, Application US/10257017B
; Publication No. US20040241651A1
; GENERAL INFORMATION:
; APPLICANT: Alexander Olek
; APPLICANT: Christian Piepenbrock
; APPLICANT: Kurt Berlin
; TITLE OF INVENTION: Detection of single nucleotide polymorphisms (SNPs) and cytosine
; FILE REFERENCE: E01/1193/WO
; CURRENT APPLICATION NUMBER: US/10/257,017B
; PRIOR FILING DATE: 2002-10-07
; PRIOR APPLICATION NUMBER: DE 10019173.8
; NUMBER OF SEQ ID NOS: 382046
; SEQ ID NO 4121
; LENGTH: 13
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Oligonucleotide for detection of SNP TSC0001541
US-10-257-017B-4121

```

Query Match 0.5%; Score 13; DB 1; Length 13;
Best Local Similarity 100.0%; Pred. No. 30;
Matches 13; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 74 AAGAGTTGTTGAA 86
DB 1 AAGAGTTGTTGAA 13

RESULT 2

```

US-10-257-017B-4122/C
; Sequence 4122, Application US/10257017B
; Publication No. US20040241651A1
; GENERAL INFORMATION:
; APPLICANT: Alexander Olek
; APPLICANT: Christian Piepenbrock
; APPLICANT: Kurt Berlin
; TITLE OF INVENTION: Detection of single nucleotide polymorphisms (SNPs) and cytosine
; FILE REFERENCE: E01/1193/WO
; CURRENT APPLICATION NUMBER: US/10/257,017B
; PRIOR FILING DATE: 2002-10-07
; PRIOR APPLICATION NUMBER: DE 10019173.8
; NUMBER OF SEQ ID NOS: 382046
; SEQ ID NO 4122
; LENGTH: 13
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Oligonucleotide for detection of SNP TSC0001541
US-10-257-017B-4122

```

Query Match 0.5%; Score 13; DB 1; Length 13;
Best Local Similarity 100.0%; Pred. No. 30;
Matches 13; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 74 AAGAGTTGTTGAA 86
DB 13 AAGAGTTGTTGAA 1

RESULT 3

```

US-10-257-017B-9699/C
; Sequence 9699, Application US/10257017B
; Publication No. US20040241651A1
; GENERAL INFORMATION:
; APPLICANT: Alexander Olek
; APPLICANT: Christian Piepenbrock
; APPLICANT: Kurt Berlin
; TITLE OF INVENTION: Detection of single nucleotide polymorphisms (SNPs) and cytosine
US-10-257-017B-9699

```

Attachment

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; TITLE OF INVENTION: methylations
; FILE REFERENCE: E01/1193/WO
; CURRENT APPLICATION NUMBER: US/10/257,017B
; PRIOR FILING DATE: 2002-10-07
; PRIOR APPLICATION NUMBER: DE 10019173.8
; NUMBER OF SEQ ID NOS: 382046
; SEQ ID NO 9699
; LENGTH: 13
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Oligonucleotide for detection of SNP TSC0002528
US-10-257-017B-9699

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Query Match 0.5%; Score 13; DB 1; Length 13;
Best Local Similarity 100.0%; Pred. No. 30;
Matches 13; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1081 CAATTCGCAAAA 1093
DB 13 CAATTCGCAAAA 1

RESULT 4

```

US-10-257-017B-9700
; Sequence 9700, Application US/10257017B
; Publication No. US20040241651A1
; GENERAL INFORMATION:
; APPLICANT: Alexander Olek
; APPLICANT: Christian Piepenbrock
; APPLICANT: Kurt Berlin
; TITLE OF INVENTION: Detection of single nucleotide polymorphisms (SNPs) and cytosine
; FILE REFERENCE: E01/1193/WO
; CURRENT APPLICATION NUMBER: US/10/257,017B
; PRIOR FILING DATE: 2002-10-07
; PRIOR APPLICATION NUMBER: DE 10019173.8
; NUMBER OF SEQ ID NOS: 382046
; SEQ ID NO 9700
; LENGTH: 13
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Oligonucleotide for detection of SNP TSC0002528
US-10-257-017B-9700

```

Query Match 0.5%; Score 13; DB 1; Length 13;
Best Local Similarity 100.0%; Pred. No. 30;
Matches 13; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1081 CAATTCGCAAAA 1093
DB 1 CAATTCGCAAAA 13

```

US-10-257-017B-12355/C
; Sequence 12355, Application US/10257017B
; Publication No. US20040241651A1
; GENERAL INFORMATION:
; APPLICANT: Alexander Olek
; APPLICANT: Christian Piepenbrock
; APPLICANT: Kurt Berlin
; TITLE OF INVENTION: Detection of single nucleotide polymorphisms (SNPs) and cytosine
; FILE REFERENCE: E01/1193/WO
; CURRENT APPLICATION NUMBER: US/10/257,017B
; PRIOR FILING DATE: 2002-10-07
; PRIOR APPLICATION NUMBER: DE 10019173.8
; NUMBER OF SEQ ID NOS: 382046
US-10-257-017B-12355

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